NUTRILITE.
DIVISION

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852
[Docket No. 99N-0391]

To Whom It Concerns:

The April 8, 1999 *Federal Register* contained a request for comment under the Docket no. listed above [*Federal Register: April 9, 1999 (Volume 64, Number 68)* Pages 17397-17399]. The Food and Drug Administration (the Agency) requested comments useful to the delegate from the United States to the *Codex Alimentarius Commission* (*Codex*). The request for comments was specific in notation of topic and in exclusion of topics that are unhelpful. This letter contains the comments from the Nutrilite Division of the Amway Corporation (Nutrilite).

The Nutrilite Division of the Amway Corporation is a leading and responsible manufacturer and distributor of quality Dietary Supplements. Nutrilite manufactures and sells Dietary Supplements in over 25 countries outside of the United States. Our sales of Dietary Supplements in the United States constitute a significant portion of our business but sales internationally account for the majority. Nutrilite has manufactured and sold Dietary Supplements in the United States for over 60 years. This provides us with historical perspective and experience that is unparalleled in the industry.

The mandates of the Nutrilite division and the entirety of the Amway Corporation include compliance with applicable regulations in the composition, manufacture, promotion and sale of all of our products, including Dietary Supplements. We are familiar with and make every effort to involve ourselves in regulatory direction and application. Our long history of marketing a wide range of Dietary Supplements and nutritious foods both domestically and internationally provides us with great perspective. Additionally, our scientists gather, study and convey the information concerning our products as part of our routine. Our foundation from the beginning is the attainment of optimal health for our consumers through provision of accurate and appropriate information, presented in simple terms in conjunction with products useful in making real health choices. This philosophy encompasses the roles of proper diet, exercise, adequate rest and the consumption of Dietary Supplements when deemed desirable. Nutrilite supplements are the finest in the world and our efforts continue to involve and advance the science behind these vital products. The combination of all the above facets of Nutrilite makes us highly qualified to comment on this proposal.

The commentary that follows begins with detailed perspective supporting the subsequent commentary for the United States delegation to *Codex*. Next, this correspondence succinctly addresses each of the topic requests (numbered 1 through 8 in the Docket) then follows on to commentary on additional topics. Each section conforms to the request of the Agency regarding the presentation of response. The purpose of this commentary is to offer the Agency and ultimately our delegate to *Codex* meaningful background useful for the approach to this important issue. The last section contains a brief summary of why the matters are of such importance and our expectations of our delegation on behalf of the responsible members of the Dietary Supplement industry.

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PERSPECTIVE

Nutrilite believes strongly in the position that Dietary Supplements play an important role in overall health. Further to this point is our perspective that Dietary Supplements are not intended as substitutes for other healthy habits nor are they a panacea for all the ills of man. The use of Dietary Supplements as part of an individual's overall program and understanding of their health is an essential component to long-term health and reduction in the incidence of chronic disease.

The most effective means by which Dietary Supplements become useful is in the education of the consumer as to their benefit in conjunction with the consumer's understanding of other health matters. This must coincide with the availability of meaningful choices in the Dietary Supplement category. These choices, both of educational presentation to the consumer and in product offering cannot be hindered by undue restriction excepting legitimate, science-based safety concerns.

Nutrilite believes that the concept of a total program for a healthy life includes Dietary Supplements to achieve the goal of bringing the diet back into balance. The attainment of this goal requires the availability of information and products. Unnecessary control of this information and product flow results in costly health effects. We concur with the findings of the United States Congress as presented in the Dietary Supplement Health and Education Act of 1994 that:

" . . . there is a link between the ingestion of certain nutrients or dietary supplements and the prevention of chronic diseases . . ."

" . . . promotion of good health and healthy lifestyles improves and extends lives while reducing health care expenditures . . ."

" . . . there is a growing need for emphasis on the dissemination of information linking nutrition and long-term good health . . ." and

" . . . dietary supplements are safe within a broad range of intake, and safety problems with the supplements are relatively rare . . ." while there is a need to take

" . . . action that protects the right of access of consumers to safe dietary supplements . . . in order to promote wellness . . ."

Nutrilite distributes its products around the world. Any infringement of trade through standards that contravene the precepts stated above, regardless of the market or the source of restriction is unacceptable. The quotations immediately preceding come from the same government with authority over this industry and the FDA. We both need to maintain this perspective in our efforts. This commentary is reflective of that position and insists that our representatives similarly bear it in mind.

TOPIC 1

Since this is the first of the series, it is important here to note that the sequence of presentation differs slightly from the request for comment. The section discussing whether there is a need for the topic resides at the end of each topic's presentation.

TERMINOLOGY

Whether these products should carry a specific moniker is unarguable. The semantics that occur influence the non-English presentation as much as the English versions. This is coupled with the perspective from Nutrilite specifically. We recognize the fact that in the United States the legal and regulatory category is Dietary Supplements. In recognition of that fact, the preceding detail used this correct term. However, it is not our first choice. Nutrilite's input to the topic is as follows:

- The preferred terminology for these products should logically be Food Supplements.

The reasons for this are simply that these products *supplement* the normal intake of *food* during the course of the day. They play a notable role in the area of diet when used to supplement food intake. The concept goes back to the position that these products intend to be adjuncts to not only the diet but to overall health practices. They are a piece of a whole. They have full intention of offering supplemental nutrition to the food consumed.

The option of narrowly identifying these products as "vitamin and mineral" supplements makes too fine a point of their potential impact. The supplementation of the diet with materials and substances for which we do not yet even have names houses the true potential for these products. Limiting the scope of the nomenclature to only vitamins and minerals does disservice to the potential for these supplements to impact positively the health of consumers.

As to whether there is a need for the topic, the answer in this commentary is a consistent yet qualified YES. The topic exists in the discussion and therefore is necessary for presentation in the background paper. The recommended position for the United States is that this topic of nomenclature be the only item remaining in the compendium at the end of the discussion. This nomenclature inclusion is only to make clear that these products need not be included in the compendium itself. Regardless of what the ultimate semantics of the descriptive term are, they have no place within the compendium itself. Thus, the simplest discussion is to:

- Eliminate the phrase "vitamin and mineral supplements;"
- Support the use of the phrase "Food Supplements" as preferential to "Dietary Supplements" and;
- Follow this with the position that Food Supplements need not be included in the *Codex*.

TOPIC 2

PURPOSE AND ROLE

The clues for presentation of the United States' position on the matter reside within the existing statutes. Without requoting DSHEA again, the simplest presentation is:

- Food Supplements serve the consumer as a part of an overall good-health program.
- Their purpose is to provide supplemental nutrients through a multitude of options for consumption.

- Food Supplements play a role in the reduction of risk for chronic, long-term disease.

- They are an adjunct and not a replacement for sound dietary habits and other lifestyle factors, but they are equally as important as any other element.

- Food Supplements exist specifically for purposes of supplying nutrients and related substances that even the best diet may lack.

- Food Supplements serve as a vehicle to convey meaningful information and knowledge to the consumer about their specific health choices.

While obviously confined in the broad definition of food, these products have no clear place within a food compendium. They are, by their definition and mandate, comprised of food substances and not comprised of additives to food substances. They supplement the diet rather than exist as the sole or principal item of any food consumption. The United States delegation to *Codex*, in recognition of these facts must insure the achievement of consensus to withdraw this topic from inclusion in the compendium.

TOPIC 3

"APPROVED NUTRIENTS"

Any listing of nutrients or other substances governed by a cumbersome legislative or compendial body does disservice to the consumer. The science of nutrition is an emerging one. However, what we do know is this:

Diets that contain large amounts of certain foods demonstrate consistently a reduction in the incidence of many long-term, debilitating, costly diseases.

Any listing, whether positive or negative, limits access to these food substances unreasonably. Approaching either form of list we find:

Positive Lists

No complete list identifying ALL the beneficial substances present in food exists. This lack of existence immediately demonstrates the folly of attempting to create one in any short-term perspective. Additive lists of nutrients that can be altered are equally as fallacious in concept as assuming one exists already. The reality of maintaining such a list with the appropriate expedience necessary to allow for effect shows that far too much time is guaranteed to elapse prior to approval sanction. When a beneficial substance in a food becomes newly identified, why should there be any delay in offering this beneficial substance? If it already exists in food, and is known to be safe, why hesitate at all? There is no real benefit to creating, maintaining or proposing any such list.

Negative Lists

The listing of substances that should NOT be included as nutrients pre-supposes that such ingredients exist. If the materials and substances under consideration exist in nature as part of food, then presentation of them as Food Supplements requires no restriction. Again, the demonstration of the emergence of science as the key to these evaluations shows here. As science understands the

relationships between substances found in food and their benefits to health, why must a layer of compendial demonstration be removed? Consumption of supplemental iodine, as a small example, is mandatory to maintain the proper health of the people of Central Europe. Yet, in much of Asia, there is little need for such supplementation. Should the consensus position be that iodine is on a negative list? There exist other such examples in the science-based world. Why deny the availability of a nutrient? What purpose can it serve? Denial of presentation of a nutrient is the same as starvation on a smaller yet specific scale. Thus, a body as august as *Codex* must play no role in this practice. The recommendation then is to continue opposition to such guidelines.

TOPIC 4

Maximum Levels

Coverage of this topic again resides in the findings of DSHEA noted earlier. These substances are safe across a broad range of intake.

However, to the particulars of the matter, there exists evidence that some few of these materials may pose at some grossly elevated levels of consumption a bit of risk. Even the qualifiers necessary to characterize this situation demonstrate the absurdity of the prospect. Ample evidence exists within the science that these nutrients are generally safe. Any attempt of this nature to politicize real science is wholly inappropriate.

Should an individual government, out of legitimate concern over the health of its people wish to act in a singular fashion there exists ample authority and reason to do so. At the local level, an individual government sits in the best position to assess the needs and requirements of its population. A general compendium of such safety limits ignores the wonder of human diversity and how this diversity yields requirements completely dissimilar from one person to another.

Review of the science does indicate that some rational limits on some individual nutrients are useful. This perspective however is one based on a review of science in its entirety rather than a simple or simplistic assertion based on minimal studies. This perspective does not politicize the issue. The essential reference paper on this issue emanated from the United States in the *American Journal of Clinical Nutrition* from Volume 66 Number 2, August, 1997 (*Vitamins and minerals: efficacy and safety; Hathcock*). This work demonstrates the only logical approach to establishing any sort of overall safe limits for these nutrients.

Codex does not have a role in this determination owing to the facts that these products and the nutrients contained in these products are overall exceptionally safe. The establishment of individual limits is a national matter for specific instance based in large measure on the population under governance. Thus, the United States must continue to oppose inclusion of this topic in *Codex*.

TOPIC 5

MINIMAL LIMITS

The challenge with setting minimal limits in the confines of a compendium is different from the setting of maximums yet they touch on the same issues. The purpose of the presentation of any Food Supplement is to provide product with meaningful levels of the nutrients offered. The challenge then comes in the definition of the word "meaningful."

The focal point again arises first with the diversity of the human animal. This diversity manifests itself in governmental interventions on dietary matters through the establishment of recommendations of nutrient intake (commonly called RDA's or RDI's). These often reflect the scientific thinking of the government regarding the needs of the people. Referencing again the iodine example, there are differing needs of the populations, in this example, of Central Europe and much of Asia. These are often reflected in the RDA or RDI level. Thus, meaningful typically relates to the matters of RDA or RDI. However, uniformity of such values is not typically present from nation to nation. Thus, the most common basis for such presentation is weak.

As a last point on the matters of minimal levels, the issue is one of defining again what is meaningful from the perspective of the current state of science. As science advances often the "less is more" approach is found appropriate. It may be argued that vitamin C for example when consumed along with the other nutrients and components found in nature (bioflavonoids, polyphenols etc.) may be more bioavailable than just plain ascorbic acid. Thus, establishment of minimal levels becomes bifurcated when consumption of a significantly lower level of the same nutrient is sufficient to achieve the same beneficial effect when consumed with the other support ingredients. In sum, such establishments are just not feasible.

Lastly on this topic is the matter of market force. There is one caveat addressed in a later topic. Overall, though, the matter of an educated consumer discerning their own requirements negates the need for the existence of arbitrary minimums. Armed with appropriate information, the consumer will elect through purchase and use meaningful Food Supplements. Thus, through market forces comes the establishment of minimum levels for any nutrient and product. This does require the allowance of information to flow to the consumer, but the choices are rightfully theirs to make and ultimately these choices set the minimums. Without the presentation of complete information, however, the determination becomes impossible. The United States must remain steadfast in opposing the inclusion of this topic in *Codex*.

TOPIC 6

PURITY AND GOOD MANUFACTURING PRACTICE

The use of Good Manufacturing Practices points to the responsibilities of the manufacturer. The concept that having such GMP in place assures everyone that the purity of the product exists is a weak assumption, however.

The establishment of some form of global GMP for Food Supplements and expecting that they be universally applied is erroneous. The challenges in identifying the basics for Food Supplement GMP are complex and diverse. Practical evidence exists today in the United States, where efforts to have industry apply self-crafted GMP led to changes even as the first implementations rolled out.

There is no place within the confines of a compendium for the strictures of GMP. The United States must continue to oppose inclusion of this topic in the process.

TOPIC 7

CLAIMS AND WARNING STATEMENTS

The matter of claims and warning statements are separate issues yet remain linked in this discussion. Taking each separately:

Claims

The overriding principle must be the presentation of truthful, accurate and complete information to the consumer regarding Food Supplements. The United States' history of these initiatives contains ample reasoning for this position. The challenge is in applying any restriction beyond that of conveyance of truth. When any claims limits are set, the limits are challenged and the danger of a lack of information grows. These determinations are best left to individual governments to establish within the framework and confines of their regulatory structure and the hands of the population. Models already exist for these governments to use. There is little need to establish yet another model. The position of the United States must continue to be staunch opposition to the inclusion of claims limits within *Codex*.

Warnings

This issue is an echo of the concerns over maximum limits. The challenge is in finding sufficient science to support warnings on a universal basis. The overall issue is one of determination of safety and presentation of safe products. The addition of warnings serves little use if the consumer is determined to partake of the product in any event. Individual governments require and are fully authorized to make determinations for their people as to the appropriateness of any warning. The United States must continue to oppose inclusion of this topic in *Codex*.

TOPIC 8

PACKAGING AND MARKETING

The matters of packaging the products classified or identified as Food Supplements are simple and logical. They need to be contained in food quality materials. These materials must include the same requirements for direct contact with any other food product. Beyond this there is little to be gained in placing restrictions within a compendium. No similar model exists within this country and thus the United States must remain opposed to inclusion of this topic in *Codex*.

Marketing of Food Supplements is a matter that crosses national boundaries, philosophies and presents notable challenges. These matters have no place within the confines of a "food code" which, ultimately, is what *Codex* purports to be.

If all discussion were available, a solid case may be made not only for the broad availability of information and products through a host of outlets, but that utilization of the direct-sell approach is a preferable method of sale for these products. This comes from the fact that the concept is in the education of the consumer toward a healthy life. This education, as with any education, occurs best in smaller settings with focused attention. The direct-sell method is superior specifically in this regard. Nonetheless, this compendium need not contain requirements or strictures on the sale of Food Supplements by any method. Thus, the United States in its efforts to insure continued free trade must oppose inclusion of this topic in *Codex*.

ADDITIONAL TOPICS

It is unfortunate that the discussions here were limited to the discussions of "vitamins and minerals." There is a host of other substances, inclusive of but not limited to botanicals that are ripe for debate. Ancillary substances commonly found in nature as a part of food are among these subjects. This continues to demonstrate the imprudence of *Codex* in attempting to include this

broad range of products under its umbrella. Scores of additional materials commonly found in foods, but which are not vitamins and minerals are worthy of discussion. However, there is no place for them in the *Codex* forum. In truth, foods in general contain an innumerable quantity of materials that benefit man. When man is able to provide these beneficial materials in a more convenient form, there should not be debate over their inclusion. So long as these substances remain available in the conventional foods we eat; they must remain equally available in Food Supplements. In fact, with the advances in science today, we may even anticipate the removal of some of these other nutrients and thus ever more require Food Supplements to provide them. The United States through its representation to the *Codex Alimentarius* Committee must drive for consensus concerning the removal of this topic for the discussion.

SUMMARY AND CONCLUSION

Since the request for commentary came from the delegation representing the United States, it is only necessary to look to the Law of the United States that governs these products. The Federal Food, Drug and Cosmetic Act with all of its amendments is the sole reference necessary in making determinations as to either the background for discussion or the nature of this nation's position. Our system of presentation and offering a host of safe products, truthful and complete information, using all of science in determination and substantiation is our foundation. It must remain the foundation for all debate and discussion of the matters affecting the regulation and/or trade of Food Supplements in any market. The United States delegation in its efforts must drive toward a consensus position that takes Food Supplements out of the mix for inclusion in *Codex*. Anything short of this misrepresents the millions of Americans who consume these products under the Law governing their safe use. Anything less than this represents undermining of trade and declination of a substantial part of the American economy. Nutrilite proudly counts itself among the responsible manufacturers and exporters of Food Supplements. We support your continued efforts to drive the *Codex* process to the benefit not only of American business but also of every consumer of these products throughout the globe.

I hope you find this commentary helpful.

Sincerely,

James C. Lassiter
Senior Manager, Technical and Regulatory Affairs

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